Amendment
Attorney Docket No. S63.2B-9178-US01

## Remarks

Claims 20-30 are allowed.

## Rejections

35 U.S.C. §112

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that there is insufficient antecedent basis for the limitation "said free radical initiator" in line 1 of the claim.

A new claim 35 has been added. Support for this claim is found on page 9 of the specification. Claim 10 has been amended such that it now depends from claim 35. No new matter has been added. Applicants respectfully request withdrawal of the rejection of claim 10 under 35 U.S.C. §112, second paragraph.

## 35 U.S.C. §103(a)

Claims 1-9, 11-19 and 31-34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Nakagawa et al. (US 6,479,584). The Office Action refers us to the discussion in section 8 of the 25 August 2003 office action (Paper No. 10/20030825) and asserts that Nakagawa et al. teach that its compositions can be used to make medical devices (col. 25, lines 61-62), the use of the polymers having ethylene and propylene backbones in its silane-reactive polymers (col. 4, line 35) and at least three of applicant's silanes:

γ-glycioxypropyltriethoxysilane (col. 16, line 62),

y-isocyanatopropyltrimethoxysilane (col. 17, line 2), and

γ-(meth)acryloxypropyltrimethoxysilane (col. 17, line 12),

but that Nakagawa fails to teach the production of catheter balloons. The Examiner asserts that in the absence of convincing objective evidence to the contrary, the use of Nakagawa's compositions to make any particular medical device is deemed to be an obvious matter of engineering choice, depending upon the properties desired in the device, and that the use of Nakagawa et al.'s compositions to make catheter balloons is deemed a matter of intended use and does not serve to distinguish such balloons from any other medical device.

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Applicants traverse the rejection.

Independent claim 1 of the present application is directed to medical devices having dilatation balloons formed from the reaction product of at least one polymer and at least one hydrolysable silane in which the resultant polymeric material is further reacted with moisture to produce a polymeric material crosslinked through

--Si--O--Si--linkages, and independent claim 12 is directed to *balloon catheters* formed from a moisture cured polymeric material crosslinked through --Si--O--Si-- linkages.

Nakagawa et al. describe a resin composition comprising a crosslinking silylterminated stellar-structure vinyl polymer or a stellar-structure vinyl block copolymer or chainextended vinyl block copolymer.

The Office Action asserts that Nakagawa et al. teach that the compositions can be used to make medical devices, (col. 25, lines 61-62).

This is incorrect. The exact statement made by Nakagawa et al. at col. 25, lines 58-62 is the following:

As specific fields of application, there may be mentioned interior and exterior parts of cars, electric and electronic sectors, food packaging films and tubes, containers or sealable articles for drugs and medical devices, etc.

Thus, what Nakagawa et al. is suggesting here, are the formation of the containers or sealable articles for drugs or medical devices, but not the formation of drugs or medical devices themselves, much less a medical device so specific as a dilatation balloon or balloon catheter.

Consequently, independent claims 1 and 12 are not obvious over Nakagawa et al. Claims 2-9, 11 and 31-34 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable. Claims 13-19 depend from claim 12 and are patentable for at least the reasons that claim 12 is patentable.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-9, 11-19 and 31-34 under 35 U.S.C. §103(a) as being obvious over Nakagawa et al., US 6,479,584.

Claim 10 has been rejected under 35 U.S.C. §103(a) as being unpatentable over

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Nakagawa et al. as applied to claims 1-9, 11-19 and 31-34 above, and further in view of Penfold (US 6,048,935). The Office Action asserts that Nakagawa et al. fail to teach organic peroxide initiators, but that it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the peroxide initiators of Penfold in Nakagawa et al.'s compositions in order to shorten their curing times.

As Nakagawa et al. do not suggest making medical devices in general, much less balloon catheters or dilatation balloons specifically, claim 1 is not obvious over Nakagawa et al. Claim 10 depends from claim 1 and is patentable for at least the reasons that claim 1 is patentable over Nakagawa et al.

Using the peroxide initiators of Penfold, in the compositions of Nakagawa et al., does not lead one of skill in the art to the balloon catheters or dilatation balloons of the present invention. The combination of references is missing a most important element of independent claim 1, i.e. the dilatation balloon.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Nakagawa et al., US 6,479,584 as applied to claims 1-9, 11-19 and 31-34 above, and further in view of Penfold (US 6,048,935).

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## CONCLUSION

Claims 1-35 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

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